Arizona Medical Board

9545 East Doubletree Ranch Road • Scottsdale, Arizona 85258
Home Page: http://www.azmdboard.org
Telephone (480) 551-2700 • Fax (480) 551-2704 • In-State Toll Free (877) 255-2212

FINAL MINUTES FOR OFFICE BASED SURGERY COMMITTEE MEETING
Held at 12:00 p.m. on August 3, 2005
9545 E. Doubletree Ranch Road · Scottsdale, Arizona

Office Based Surgery Committee Members
William R. Martin III, M.D.
Ram R. Krishna, M.D.
Douglas D. Lee, M.D.

CALL TO ORDER
William R. Martin III, M.D., Chair, called the meeting to order at 12:00 p.m.

ROLL CALL
The following Committee Members were present: William R. Martin III, M.D., Douglas D. Lee, M.D. and Ram R. Krishna, M.D.

Staff Members Present
Timothy C. Miller, J.D., Executive Director, and Lisa McGrane, Investigational Review Manager.

Board Counsel, Christine Cassetta, Assistant Attorney General, was also present.

CALL TO THE PUBLIC
The following people were present for Call to the Public, but did not speak: Stacey Gaus, Williams & Associates/ Arizona Association of Nurse Anesthetists, Mike Pryor, President, Williams & Associates / Arizona Association of Nurse Anesthetists, and Sarah Swoboda, American Society of Plastic Surgeons

Approval of July 16, 2005 Stakeholder Meeting Minutes
Timothy C. Miller, J.D., made a correction to the minutes regarding Larry Lanier's comments on page 2: Mr. Lanier's position is there have been instances in the past where using local and topical anesthetics has created toxicity problems, but he does not believe it requires regulation. Dr. Martin's recollection of Mr. Lanier's statement was the same.

Stacey Gaus apologized for missing the Call to the Public and requested an opportunity to add a comment regarding the minutes. In regard to Dr. Leib's comments on page 2 that state the use of Propofol be prohibited, except by Anesthesiologists, Ms. Gaus didn't recall him saying that it was exclusively for anesthesiologists. She thought he said it was by a trained professional, which would include a nurse or anesthetist. Mr. Miller and Dr. Martin remembered Dr. Lieb's comments the same way.

MOTION: William R. Martin III, M.D. moved to accept the July 16, 2006 Office Based Surgery Stakeholder meeting minutes with the noted corrections.
SECOND: Ram R. Krishna, M.D.
VOTE: 3-yay, 0-nay
MOTION PASSED.

Stakeholder Comments

William R. Martin III, M.D. suggested using the version of rules sent to the Committee by Lisa McGrane that incorporated the stakeholder comments from the draft minutes, as a guide. All Committee members agreed.

Article 1. General Provisions

Dr. Martin started with the first question submitted by Timothy C. Miller, E.D., “Do you think the rules should require admitting privileges or have transfer agreements with a local hospital?"

Dr. Krishna did not think it was necessary because hospitals will take a patient as an emergency. Ms. Cassetta stated this was also addressed under provision R4-16-708(5). All Committee members agreed the rules did not need to require admitting privileges.

R4-16-101 Definitions.

Dr. Martin asked Mr. Miller to give an overview of what the Department of Health Services (DHS) is doing regarding rules for medical facilities.

Mr. Miller stated that DHS has statutory authority to regulate all medical facilities. The initial definition of medical facilities is any building where healthcare services are provided. There is an exception for a doctor’s office; however, it does not apply to doctor’s offices that use general anesthesia. If a physician uses general anesthesia in the office then they need a license from DHS.

DHS notified Mr. Miller they were starting to write their Ambulatory Surgical Center Rules for outpatient surgery. This is their name for Office Based Surgery practice. DHS takes the stand that if physicians never use general anesthesia in their practice then they will not have to comply with the DHS rules, but the Arizona Medical Board (AMB) rules will still be applicable.

The definition of “general anesthesia” needs to be resolved. DHS was looking at the Board’s definition for deep sedation as a possible definition for general anesthesia. The Committee has several definitions of general anesthesia from various sources that all agree that it is a loss of consciousness not a depression of consciousness. Mr. Miller will work with DHS on initially establishing the definition for general anesthesia. Mr. Miller feels these rules need their own definition of general anesthesia.

DHS will also write more extensive requirements about what a facility has to have in it such as equipment, training of non-medical staff, and other issues. Mr. Miller recommends to the Committee that the Board concentrate on the absolute minimum requirements for these issues necessary for deep sedation, minimal sedation, and moderate sedation. He will talk to DHS about adopting those as the absolute minimum for all forms of sedation and anesthesia. The Board would set the standard for these three levels for deep, minimum and moderate sedation and DHS could set the standards beyond that.

Ms. Cassetta noted that the only area where there would be any overlap of rules as currently written by DHS is in the equipment section. The remaining rules specifically address what is required of physicians, not of the facility itself. This will reduce conflict with any proposed DHS rules.

Mr. Miller stated that if the Board concentrates on office based surgery as it relates to physicians, there will be less to coordinate with DHS. All Committee members agreed.

Dr. Martin discussed Dr. Leib’s suggested definitions for deep sedation, minimum sedation, and moderate sedation from the previous meeting. Both Dr. Martin and Dr. Krishna felt these were reasonable inclusions. Dr. Lee felt that Dr. Leib’s definitions were very well spelled out, they were similar to the Joint Commission on Accreditation of Healthcare Organization’s (JCAHO’s) wording, and they should be included. The suggested definitions are:

> “Deep Sedation” is a drug-induced depression of consciousness during which patients cannot be easily aroused, but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
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> “Minimal Sedation” (Anxiolysis) is a drug-induced state where patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.
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> “Moderate Sedation/Analgesia” (Conscious Sedation) is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Dr. Martin discussed adding a definition for General Anesthesia to this section. Mr. Miller agreed and read a definition for General Anesthesia.”

"General Anesthesia" is a drug-induced loss of consciousness during which patients cannot be aroused, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Dr. Martin felt this definition was reasonable. Dr. Lee and Dr. Krishna agreed that it should be in this section and that it was well written.

Article 7. Office based Surgery

Dr. Martin read the Joint Commission's suggestion: state licensure, national accreditation or both be required to allow general anesthesia in the facilities, except dental offices, where general anesthesia is used to obtain and maintain a license. DHS accepts JCAHO accreditation in lieu of licensure.

Dr. Krishna stated that if the level of anesthesia is dictated for someone who is planning to do general anesthesia, it should be American Association of Ambulatory Surgery Centers (AAASC) or DHS accredited.

Dr. Lee stated that anesthesia, when performed overtly, should be done in a facility that is licensed and certified, Medicare certified, or some other regulated facility. He doesn't believe there are facilities, other than dental offices, that do general anesthesia in an office based non-regulated facility in Arizona. Dr. Krishna felt the Committee still needed to require Board licensed physicians to perform general anesthesia in offices that are accredited. Dr. Lee noted that the Board does not have jurisdiction over dental offices.

Mr. Miller reminded the Committee that DHS is writing rules for facilities that use general anesthesia. One provision of the rules that DHS will touch on is the option of a facility becoming JCAHO or AAASC accredited in which case the state would issue them a license under a deemed status in lieu of the facility obtaining a state license. DHS gives an option to the facilities to choose which way to go. DHS does not mandate that a facility must be accredited by one of these other organizations. If the facility does not use general anesthesia it does not fall under DHS jurisdiction and it falls to the Board to determine whether or not accreditation is necessary.

Dr. Lee clarified that the reason he put the issue of the use of general anesthesia by oral surgical offices on record is because there are a number of oral surgeons that are dental oral surgeons as well as M.D.s. Dr. Krishna replied that as long as they are licensed by the Board and practicing as an M.D. they should follow Board rules and regulations. Dr. Lee felt that it could potentially be a problem that if the physician was doing wisdom teeth in his office not as an M.D. but as an oral surgeon, then his facility might not be licensed when he is doing general anesthesia. Dr. Krishna said the physician would still be under the Board's jurisdiction.

Dr. Krishna felt the Board should put in a requirement for accreditation even though DHS is doing it. DHS will be able to see what the Board has done and duplicate it if they want. If the Board does not put it in, it might mislead some of the physicians, as to which organization to follow, it is better for the Board to be complete and put it in. Dr. Martin and Dr. Lee agreed.

Mr. Miller summarized that facilities that use general anesthesia should receive accreditation by some nationally recognized accreditation organization, or be licensed by DHS. Dr. Krishna added that Medicaid or Medicare should be added because they are as good as AAASC or JCHAO accreditations and they are well recognized. All agreed.

Dr. Martin read the Arizona Hospital and Healthcare Association (AzHHA) suggestion: The rules should allow for the Board to make periodic site inspections to ensure the facilities, rather than the licensee, is in compliance.

Christine Cassetta, Assistant Attorney General said facility inspection was beyond the scope of AMB's authority. Mr. Miller noted it is DHS's responsibility to inspect the facilities. The Board can require the doctor to ensure that the facility meets these requirements because the Board retains jurisdiction over the physician. If an investigation determines there is something wrong with the facility then the Board can take action.

The Committee does not feel it is necessary to add this to the rules.

R4-16-702. Anesthetic Monitoring Standards. Minimum Sedation; Moderate Sedation; Deep Sedation

Dr. Martin read Mary Griffith's recommendation: Monitoring should be the same for both moderate and deep sedation.

Dr. Lee felt that the Committee should approach the minimum basic monitoring of anesthesia using the American Society of Anesthesiologists (ASA) standards. In past discussions it was felt this was too onerous and anesthesiologists must be held to those standards, but others may not need to be. Dr. Lee felt all basic monitoring should be basic. Moderate to deep sedation should include all the things we need to measure for respiration and oxygenation.

Mr. Miller read (3(b)) Deep sedation. “Ensure a licensed healthcare professional whose sole responsibility is attending to the patient is present throughout the entire procedure.” He asked Dr. Lee if this is also needed under (2) for moderate sedation? Dr. Lee felt it should be under both moderate and deep. The nursing advisory suggested if it is a nurse, for example, providing the sedation that the nurse should have no additional responsibilities other than attending to the patient as drugs are being administered and during the period of time that the drug is having it’s affect. Dr. Lee felt that strictly from a patient safety standpoint, it is a reasonable standard. Dr. Martin and Dr. Krishna agreed that it should be added.

The Committee concluded that section (2) and (3) should be combined and read as Moderate and Deep sedation and that subsection (3(b)) should become an additional subsection of section (2).

Dr. Martin read the additional suggestions for this section:

Ms. Griffith submitted a Board of Nursing advisory letter on the scope of practice for RNs in administering and monitoring conscious sedation.

Dr. Brill suggested identifying who qualifies as a licensed health care professional. The Committee suggested adding “and qualified” after licensed. The Committee discussed that the monitoring is in addition to the physician who performed the procedure.

Ms. Cassetta offered language that would address the Committee’s concern about “monitoring is in addition to the physician who performed the procedure.” The language would read, “Ensure a licensed healthcare professional, other than the physician, whose sole responsibility is attending to the patient is present throughout the entire procedure.

Dr. Lee asked if it would create a problem if we added “and qualified”. Dr. Martin replied that it came up in the last meeting because a person may be licensed as a dog-catcher, for example, but may not be appropriately licensed to administer anesthesia. Ms. Cassetta felt it would not be a problem to add it and it would not contradict anything later.

The Committee agreed to add “and qualified” to section (3(b)) that will become (2(d)) after the two sections are combined.

Mr. Miller suggested having the physician be responsible for ensuring that who they use is qualified so that the Board is not the one deciding that. The burden is then placed on the physician to figure out who is qualified. If an investigation ever arises or it comes to the Board, the Board could always ask how the physician determined that the person was qualified. Ms. Cassetta noted that otherwise the Board would be faced with defining “qualified” in the definitions and listing the specific specialties.

Dr. Martin referred to the suggestion from AzHHA suggesting physicians be required to provide proof of training in the administration of sedatives and anesthetic agents.

Dr. Martin felt proof of training, was adequately addressed in R4-16-704 section 5. Ms. Cassetta agreed and noted the ASA is saying the physician has to prove they have trained people in the administration of sedatives and anesthetic agents.

Mr. Miller noted that by saying “qualified” the burden is put on the physician to do that without being told how to do it. This is getting more into telling the physician how to qualify them rather than leaving it up to the physician to figure that out.

Dr. Lee felt it should be left loose enough for the physician to make that definition. If it came to the Board, ultimately the Board would decide whether or not the dogcatcher that the physician said was qualified, was or was not qualified.

Mr. Miller added that if it ever comes to the Board, the Board can always ask the physician how was it determined that this person was qualified and what training background did the person have to base that decision on.

Ms. Cassetta said it brings into play the act of unprofessional conduct for lack of or inappropriate direction or collaboration with a licensed professional.

Dr. Lee reiterated to leave it loose enough for the physician to be able to determine what that qualification is, although the Board reserves the right to adjudicate that decision. The Committee agreed to leave it as a “licensed and qualified healthcare professional” and did not want to add anything additional to the section.

R4-16-703. Anesthetic Monitoring Standards: General Anesthesia, section A

Dr. Martin read the stakeholders suggestion: “and major nerve block” should be added after anesthesia in section A.

Dr. Martin discussed the comments from Dr. Lee’s colleagues at the last meeting, who felt that complications could arise from doing a major nerve block, which could necessitate the Board needing to be involved in terms of regulation.

Dr. Lee said major nerve block theoretically includes central neurological blockade that could be spinal epidurals. It can be interpreted as major regional as well as interscaling blocks, things that could put respiration in jeopardy, or other blocks similar to that.

Dr. Krishna added that another concern involved multiple layers of local infiltrations, such as liposuction, could give a massive dose of local infiltrations all over. Dr. Lee wasn't sure how to approach that. Dr. Lee stated that local infiltration is local anesthetic, and it is used in a defined and studied manner by the plastic surgeons and dermatologists.

Ms. Cassetta referred to the statute that authorized the rules and definition of office based surgery that says "a medical procedure using intravenous sedation." Ms. Cassetta asked if the blocks would fall under this definition. Dr. Lee said they would not by definition, nor does a spinal epidural, which is considered a major conduction anesthetic with or without sedation. But, in an anesthesiologist's mind, a spinal epidural anesthetic is equivalent to a general anesthetic in terms of the cardiovascular respiratory dysfunctions that can occur. It doesn't by definition mean intravenous.

Dr. Martin asked if the Board needed to go back and redefine what office-based surgery is. Ms. Cassetta felt that was a possibility, but if the Committee felt that the blocks have the same affect and the potential for patient danger the Committee could add it.

Dr. Lee felt the overriding issue is patient safety under office based surgical circumstances. Whether it is intravenous technically, ventilational for general anesthetic, or intrisical for spinal. The patient safety issues are the same.

The Committee agreed to add the clause "and major nerve block" after anesthesia.

Committee members discussed broadening the term to include "intravenous general anesthesia or sedation and major nerve blocks". Ms. Cassetta said she would come up with some suggested language for office-based surgery for the next meeting.

Mr. Miller said he would provide a definition for major nerve block at the next meeting on August 10th.

Dr. Martin read Dr. Krishna's idea of doing local anesthetics in multiple areas and topical anesthetics and how or whether or not it should be considered with the rules.

Dr. Krishna expressed Dr. Leib's concern with this, because the physicians could bypass the Board's requirements and try do everything locally for a major procedure using multiple levels of local anesthetics. This could cause some toxicity problems.

Dr. Lee said that doing multiple levels of topical anesthetics without sedation could cause problems. The Committee was not sure where to put that in the rules or if it should be regulated.

Dr. Martin said that topicals could be used by someone performing liposuction in two or three different areas and that toxicities may result from doing that. If that patient were having multiple levels they might be better off with general anesthetic or sedation. With the Board rules as written, a doctor could float by it by just giving a local anesthetic instead. That patient is just as much at risk as some of the others are.

Mr. Miller asked if doctors tried to circumvent these rules by using local anesthetic, would they be dropping below the standard of care? Dr. Krishna did not think they would be. Dr. Martin thought plastic surgeons or dermatologists have a set of guidelines for liposuction, and if they fell below those standards then they would be dropping below the standard of care. Ms. Cassetta stated that the physician would be held to the community standard.

Dr. Krishna asked if the Board could put amounts not to exceed. Dr. Martin said that if the Board put down a larger dosage then what the manufacturer suggests, it may be a problem.

Ms. Cassetta felt that the Committee needed to address the basics and control the issue in general and use other ways through the standard of care and other statutes to regulate the people that try to avoid the Rules by doing it a different way. The Committee agreed to not address the issue of topical anesthetics.

R4-16-703. Anesthetic Monitoring Standards: General Anesthesia, section B, subsection 5

Dr. Martin read the suggestion by Dr. Leib to delete this provision: EKG pulse oximetry and blood pressure may be more appropriate [as a monitor than just exhaled carbon dioxide].

Dr. Martin said the FIO2 monitor is a failsafe system that ensures the content being delivered.
Ms. Cassetta referred back to R4-16-702 that talks about the monitoring that is required for general anesthesia.

Dr. Lee stated that Dr. Leib is correct in that there is no reason to have those first items listed because it is already listed. General anesthesia requires FIO2 and CO2 monitoring.

The Committee changed “regional” to “general” and left the rest as is in section B.5.

R4-16-704. Administrative Provisions

Dr. Martin read Dr. Brill’s suggestion of adding “safe and” before orderly in section A.2. The Committee agreed to add it.

Dr. Martin read the section 6 suggestion of replacing “human rights” with obtaining informed consent for performing the procedure as well as performing the procedure in an office based environment.

Mr. Miller said the Maricopa Medical Society asked what was meant by “human rights” and what information does a patient need in order to consent.

Mr. Miller said he would fill in the description for “human rights” for the next meeting.

Ms. Cassetta suggested adding “and obtains conformed consent.” Dr. Martin preferred this option and Ms. Cassetta agreed to draft it.

R4-16-705. Procedure and Patient Selection.

Dr. Martin questioned whether or not the Board needed to have separate provision for Propofol alone added to section A.1. Dr. Lee feels the Board need not specify any medication in general, but more the principle. The Committee agreed.

Dr. Martin reviewed the AzHHA suggestions in section 705 and 706 and felt that the comments were not substantive enough to require changes.

Mr. Miller felt they were more of a facility requirement that would be addressed by DHS during their rulemaking process. The assumption is doctors have to appropriately select their patients regardless of what risk categories the doctor uses.

The Committee agreed to leave these sections as is.

R4-16-707. Equipment.

DHS is going to address this and will give a more expansive list. The Committee agreed that the minimum listed is reasonable and appropriate for the Board’s rules.

R4-16-708. Emergency and Transfer Provision

Dr. Martin determined that this was already addressed today and that 911 would be the preferred method. The Committee agreed.

Dr. Martin briefly pointed out that Committee Members received many emails in the past few weeks from stakeholders. The Committee appreciates the comments and would like to thank everyone for sending them. The Committee felt everything had been covered very well.

The meeting adjourned at 12:56 p.m.

[Seal]

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Timothy C. Miller, J.D., Executive Director